SUPPORT FOR THE AMENDMENTS

Support for the amendments to Claims 8, 15 and 22 is found in original Claim 8.

New Claims 31-38 are supported by original Claims 3 and 5-11 respectively.

No new matter will be added to this application by entry of this amendment.

Claims 1-38 are active.

RESPONSE TO THE RESTRICTION REQUIREMENT

The claims have been divided into Groups as follows:

Group I: Claim(s) 1-3, 5-8, 10-22, drawn to factor X analogues in which Thr-Arg-Ile at the activation site is replaced, DNA encoding said analogs, and methods of making and using said analogues.

Group II: Claim(s) 23-24, drawn to a method of treating coagulopathy utilizing said analogue.

Group III: Claim(s) 4, 25-30, drawn to factor X analogues which can be obtained by a cleavage of factor X analogues wherein said factor X analogues are those recited in Group I, DNA encoding said analogues and methods of making and using said analogues.

Group IV: Claim(s) 4, 25-30, drawn to factor X analogues which can be obtained by a cleavage of factor X analogue analogues, DNA encoding said analogues and methods of making and using said analogues.

In addition, if Group I or II is elected, an election of a specific SEQ ID NO: 31 is required as indicated:

Election: A single sequence representing SEQ ID NO: 31, fully identifying all residues is required.

Applicants elect with traverse Group I, Claims 1-3, 5-8, 10-22, for examination. As the single sequence representing SEQ ID NO: 31, Applicants elect the sequence Val-Pro-Arg-Ala-Val-Gly (SEQ ID NO: 9).

Applicants respectfully note that Claim 9 was not included in any of the original Groups. Claim 10 depends from Claim 9 and therefore Claim 9 should be included in the elected Claims.

Moreover, Claims 23 and 24 describe a use of the factor X analogue described in Claims 1-3 and 5-22. Applicants respectfully note that the above identified application is the national stage of PCT/EP03/07793 and that 37 C.F.R. § 1.475(b) states in pertinent part:

> "An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
>
> (3) A product, a process specially adapted for the manufacture of the said product, and a use of said product; . . ."

Applicants respectfully note that Claims 23 and 24 indirectly depend from Claim 1 and according to 37 C.F.R. § 1.475(b) should therefore be examined with Claims 1-3 and 5-22.

Applicants respectfully note that new Claims 31-38 correspond to the elected claims wherein SEQ ID NO: 31 is fully defined according to SEQ ID NO: 9.

Restriction is only proper if the claims of the restricted groups are independent or patentably distinct and there would be a serious burden placed on the examiner if restriction is not required (MPEP § 803). The burden is on the Examiner to provide reasons and/or examples to support any conclusions in regard to patentable distinction. Moreover when making lack of unity of invention, in a national stage application, the Examiner has the burden of explaining why each group lacks unity with each other group (i.e. why there is no single inventive concept), specifically describing the unique special technical feature in each group (MPEP § 1893.03(d)).

The Office has asserted that Groups I - IV do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding technical features. The examiner has stated:

> "the special technical features of Groups I, III-IV are factor X analogue with Thr-Arg-Ile at the cleavage site, a factor X analogue which is obtained by cleavage of said Group I factor X analogue and a factor X analogue which is obtained by cleavage of said Group I factor X analogue analogue, which are each products of unrelated chemical structure and function and share no common feature. Group I-II share a special technical feature, namely factor X analogue."

Annex B of the Administrative Instructions under the PCT at (b) Technical Relationship states:

> "The expression "special technical features" is defined in Rule 13.2 as meaning those technical features that defines a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any)."

Applicants respectfully submit that the Examiner has not provided any indication that the contents of the claims interpreted in light of the description was considered in making the assertion of a lack of unity and therefore has not met the burden necessary to support the assertion.

Moreover, Applicants respectfully submit that independent Claims 1 and 4 share the common technical feature described in SEQ ID NO: 31, namely the thrombin-cleavable sequence Pro-Arg-Ala at the activation site.

Annex B of the Administrative Instructions Under the PCT, paragraph (c), which states in part, "Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims." Applicants respectfully submit that Claims 2-3 and 5-30 all depend directly or indirectly from Claims 1 and 4 in this application.

The MPEP (§1850) states:

> "Although lack of unity of invention should certainly be raised in clear cases, it should neither be raised nor maintained on the basis of a narrow, literal or academic approach. There should be a broad, practical consideration of the degree of

> interdependence of the alternatives presented, in relation to the state of the art as revealed by the international search or in accordance with PCT Article 33(6) . . ."

Applicants submit that the Office has not applied the same standard of unity of invention as the International Preliminary Examination Authority, which did not take the position that unity of invention was lacking in the International application and examined all the claims together.

Accordingly, and for all of the above reasons, Applicants respectfully submit that the Office has failed to meet the burden necessary in order to sustain the requirement for restriction under the rules of unity of invention. Applicants therefore request that the requirement for restriction be withdrawn.

Applicants respectfully submit that the above-identified application is now in condition for examination on the merits and early notice of such action is earnestly solicited.

Respectfully submitted,

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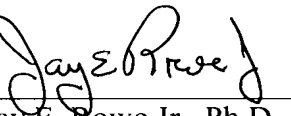

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